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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS-2012-0019]

RIN 0583-AD49

Eligibility of the Republic of Korea to Export Poultry
Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to add the Republic of Korea (Korea) to the list of countries eligible to export poultry products to the United States. Reviews by FSIS of Korea's laws, regulations, and inspection implementation show that its poultry inspection system requirements are equivalent to the Poultry Products Inspection Act (PPIA) and its implementing regulations. Under this proposal, slaughtered poultry or parts or other products thereof processed in certified Korean establishments would be eligible for export to the United States. All such products would be subject to re-inspection at United States ports-of-entry by FSIS inspectors.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

DOCKET: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Andreas Keller, Director, International Equivalence Staff, Office of International Affairs; telephone (202)690-5646.

SUPPLEMENTARY INFORMATION:

Background

FSIS is proposing to amend its poultry products inspection regulations to add Korea to the list of countries eligible to export poultry products to the United States (9 CFR 381.196(b)). Korea is not currently listed as eligible to export such products to the United States.

Statutory Basis for Proposed Action

Section 17 of the PPIA (21 U.S.C. 466) prohibits importation into the United States of slaughtered poultry, or parts or products thereof, of any kind unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient that renders them unhealthful, unwholesome, adulterated, or unfit for human food. Under the PPIA and the regulations that implement it, poultry products imported into the United States must be produced under

standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States. Section 381.196 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export poultry and poultry products to the United States.

Section 381.196(a) requires a foreign country's poultry inspection system to include standards equivalent to those of the United States and to provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's legal authority and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem and post-mortem inspection by, or under the direct supervision of, a veterinarian; (2) official controls by the national government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering of poultry and processing of poultry products by inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product

at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the PPIA and its implementing regulations (9 CFR 381.196(a)(2)(ii)).

In addition to a foreign country's legal authority and regulations, the program itself must be equivalent to the United States. Specifically, the program organized and administered by the national government must impose requirements equivalent to those of the United States with respect to: (1) organizational structure and staffing, so as to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) ultimate control and supervision by the national government over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification and residue standards; and (7) any other inspection requirements (9 CFR 381.196(a)(2)(i)).

The foreign country's inspection system must ensure that establishments preparing poultry or poultry products for export to the United States, and their products, comply with

requirements equivalent to those of the PPIA and the regulations promulgated by FSIS under the authority of that statute. The foreign country certifies the appropriate establishments as having met the required standards and advises FSIS of those establishments that are certified or removed from certification. Before FSIS will grant approval to the country to export poultry or poultry products to the United States, FSIS must first determine that reliance can be placed on the certification of establishments by the foreign country.

As indicated above, a foreign country's inspection system must be evaluated by FSIS before eligibility to export poultry products to the United States can be granted. This evaluation consists of two processes: a document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to effect its inspection program. To help the country in organizing its material, FSIS provides the country with a series of questions asking for detailed information about the country's inspection practices and procedures in six areas or equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, (5) Chemical Residue Testing Programs, and (6) Microbiological Testing Programs. FSIS

evaluates the information submitted to verify that the critical points in the six equivalence components are addressed satisfactorily with respect to standards, activities, resources, and enforcement. If the document review is satisfactory, an on-site review is scheduled using a multi-disciplinary team to evaluate all aspects of the country's inspection program. This comprehensive process is described more fully on the FSIS Web site at

http://www.fsis.usda.gov/Regulations_and_Policies/equivalence_process/index.asp.

The PPIA and implementing regulations require that foreign countries be listed in the CFR as eligible to import poultry products into the United States. FSIS must engage in rulemaking to list a country as eligible. Countries found eligible to import poultry or poultry products into the United States are listed in the poultry inspection regulations at 9 CFR 381.196(b). Once listed, it is the responsibility of the eligible country to certify that establishments meet the requirements to export poultry or poultry products to the United States and to ensure that products from these establishments are safe, wholesome, and not misbranded. To verify that products imported into the United States are safe, wholesome, and properly labeled and packaged, FSIS re-inspects and randomly

samples those products before they enter the United States commerce.

Evaluation of the Korean Poultry Inspection System

In 2005, the government of Korea requested approval to export poultry products to the United States. If approved, Korea stated its immediate intention to export two types of ginseng chicken stew products to the U.S.:

- Jeukseok Samgyetang (instant ginseng chicken stew). Instant ginseng chicken stew is packed in a retort pouch, heat pasteurized, and stored and transported as a frozen poultry product. This is a ready-to-eat (RTE) poultry product.
- Gohyang Samgyetang (hometown ginseng chicken stew). Hometown ginseng chicken stew is a sterilized retort product, which is shelf-stable. This is a RTE poultry product.

The ginseng used for the production of both poultry products, is an Oriental ginseng (Panax ginseng) and is added as a whole food and not as an extract. Therefore, it is not subject to premarket approval by the United States Food and Drug Administration (FDA).

FSIS conducted a review of Korea's poultry (slaughter and processing) inspection system to determine whether it is equivalent to the United States' poultry inspection system. As indicated above, once a foreign country's system is determined equivalent to that of the United States, that country is eligible to import into the United States any poultry product. That is, a country is not then limited to importing a certain type of product, in this case, ginseng chicken stew.

In October 2008, FSIS conducted the first on-site audit of Korea's poultry inspection system to evaluate the performance of the government of Korea with respect to the establishments it is proposing to certify as eligible to export poultry products to the United States. The audit resulted in the identification of systemic deficiencies within the following five equivalence components (as identified by component number): (1) Government Oversight, (3) Sanitation, (4) HACCP, (5) Chemical Residue Testing Programs, and (6) Microbiological Testing Programs. The audit findings stated that with regard to Component 1, Government Oversight, the central competent authority (CCA) did not have adequate government oversight and administrative controls over the inspection system. Inspection activities were being conducted by non-government employees who were paid by the establishment, and the CCA did not provide evidence to

demonstrate direct and continuous official supervision by the assigned government inspectors of processing activities for poultry products to ensure that adulterated or misbranded poultry products are not prepared for export to the United States. Regarding Component 3, Sanitation, there was a failure to implement and verify sanitation programs within the system. Likewise, for Component 4, HACCP, there was a failure to implement and verify HACCP requirements within the system. Lastly, with regard to Components 5 and 6 on Chemical Residue Testing Programs and Microbiological Testing Programs, the FSIS auditors were unable to visit any of Korea's official laboratories that conducted chemical or microbiological analyses of poultry products.

Following the 2008 on-site audit, Korea provided a corrective action plan addressing the findings identified during the 2008 on-site audit. FSIS reviewed the corrective action plan and concluded that Korea had not satisfactorily addressed all the audit findings.

In November 2010, FSIS conducted a second on-site audit, which was more comprehensive than the audit conducted in 2008, which did not include a review of Korean laboratories. The 2010 audit was conducted to verify that Korea had satisfactorily implemented all the laws, regulations, and other issuances that

FSIS found to be equivalent during the document analysis and to verify that the outstanding issues identified during the previous audit had been resolved. The 2010 audit resulted in the identification of systemic deficiencies within the equivalence components of: (2) Statutory Authority and Food Safety Regulations, (5) Chemical Residue Testing Programs, and (6) Microbiological Testing Programs. Specifically, the 2010 audit findings stated that with regard to Component 2, Statutory Authority and Food Safety Regulations, the CCA did not provide adequate control of establishment facilities for post-mortem inspection. With regard to Component 5, Chemical Residue Testing Programs, the CCA did not provide adequate control over the implementation of laboratory quality systems within its National Residue Program. Finally, with regard to Component 6, Microbiological Testing Programs, the CCA did not provide adequate controls over the implementation of laboratory quality systems associated with microbiological testing of product which is intended for export to the U.S.

Following the 2010 on-site audit, Korea provided a comprehensive corrective action plan that addressed the findings identified during the 2010 on-site audit. FSIS reviewed Korea's corrective action plan and concluded that Korea had satisfactorily addressed all audit findings. In addition, the

November 2010 audit and the subsequent corrective action plan satisfactorily addressed all the findings of the October 2008 and November 2010 audits.

In summary, FSIS has completed the document review, on-site audits, and verification of corrective actions as part of the equivalence process, and all outstanding issues have been resolved. FSIS has determined that, as implemented, Korea's poultry inspection system (slaughter and processing) is equivalent to the United States' poultry inspection system. The full report on Korea's poultry inspection system (slaughter and processing) can be found on the FSIS Web site at:

http://www.fsis.usda.gov/regulations/foreign_audit_reports/index.asp.

Should this rule become final, the government of Korea must certify to FSIS those establishments that wish to export poultry products to the United States and that operate in accordance with requirements equivalent to that of the United States. FSIS will verify that the establishments certified by Korea's government are meeting the United States requirements through verification audits of Korea's poultry inspection system.

Although a foreign country may be listed in FSIS regulations as eligible to export poultry to the United States, the exporting country's products must also comply with all other

applicable requirements of the United States. These requirements include restrictions under 9 CFR part 94 of the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulations, which also regulate the exportation of poultry products from foreign countries to the United States.

If this proposed rule is adopted, all slaughtered poultry, or parts and products thereof, exported to the United States from Korea will be subject to re-inspection at the U.S. ports-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count.

In addition, FSIS will conduct other types of re-inspection activities, such as incubation of canned products to ensure product safety and taking product samples for laboratory analysis for the detection of drug and chemical residues, pathogens, species, and product composition. Products that pass re-inspection will be stamped with the official United States mark of inspection and allowed to enter United States commerce. If they do not meet United States requirements, they will be refused entry and within 45 days must be exported to the country of origin, destroyed, or converted to animal food (subject to approval of FDA), depending on the violation. The import re-inspection activities can be found on the FSIS Web site at

http://www.fsis.usda.gov/regulations_and_policies/fsis_import_reinspection/index.asp

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866 by the Office of Management and Budget (OMB) and has been determined to be not significant for purposes of E.O. 12866.

Economic Impact Analysis

This proposed rule would add Korea to the list of countries eligible to export poultry products into the United States. Korea is seeking to export two types of ginseng chicken stew products to the United States. Given the limited market in the United States for this product, and the projected export volume of this product from Korea, the impact on the United States economy is likely to be very small. According to data from Korea, only two Korean establishments are interested in exporting ginseng chicken stew to the United States. The average combined annual production of these two establishments is 3.2 million pounds (2006-2010 average), and their projected total export to the United States will be about 380,000 pounds in year one (the first year of exporting to the United States), gradually increasing to about 2.25 millions pounds in year five, based on data from Korea.

Ginseng chicken stew is sold commercially in frozen pouches. The United States market for ginseng chicken stew is so small that no data on domestic production, consumption, or importation could be found. Using label application data, FSIS identified two official establishments that produce and sell ginseng chicken stew. Based on information from these establishments, FSIS believes (1) they are very likely the only two establishments that are producing ginseng chicken stew in the United States, (2) the market for ginseng chicken stew is limited, (3) the annual production is about 18,000 pouches for one establishment and 10,000 pouches for the other, and (4) each pouch weighs about two pounds. Therefore, the combined production of these two establishments is about 56,000 pounds per year $((18,000 + 10,000) \times 2)$. The special flavor and taste make ginseng chicken stew unlikely to be a substitute for other kinds of chicken stew in the United States. Therefore, although this rule may affect these two U.S. establishments, the impact to the United States economy is likely to be insignificant.

Expected benefits from this proposed rule will accrue primarily to consumers in the form of more choices in the marketplace. As mentioned above, the volume of trade stimulated by the proposed rule is likely to be so small as to have little effect on supply and prices. Another potential benefit of this

proposed rule would come from efficiency gains. The United States producers could become more efficient with increased competition from Korea.

The cost of this rule would be incurred by domestic producers in the form of competition from Korea. Indeed, should this rule become final, the two establishments that are currently producing ginseng chicken stew are likely to encounter competition pressure, for the projected import volume in year one is already 6.8 times the combined production volume of these two establishments. The imported volume, however, is likely to have little impact on the overall United States economy. Also, these two establishments may change their production mix if they find it difficult to compete with imports.

Effect on Small Entities

The FSIS Administrator has made a preliminary determination that this proposed rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). As mentioned above, the expected trade volume will be very small, and the effect will be on only two very small establishments that produce ginseng chicken stew domestically.

Potential Long-term Effect

When foreign countries apply for equivalence of their meat, poultry, or egg product inspection systems, FSIS determines whether their inspection systems are equivalent to the system maintained by the United States. FSIS does not make equivalence determinations on the basis of particular products; rather, the equivalence decision is based on the evaluation of the foreign countries' inspection systems.

Although Korea indicates that it intends to export two types of ginseng chicken stew products for now, it would not be precluded from exporting other poultry products in the future if the products meet all Animal and Plant Health Inspection Service (APHIS) requirements and any applicable FSIS regulations for those products. Therefore, the long-term economic impact could be larger and more complex than can be assessed now.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted:

- (1) all State and local laws and regulations that are inconsistent with this rule will be preempted;
- (2) no retroactive effect will be given to this rule; and
- (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export poultry and poultry products to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. FSIS provided Korea with questionnaires asking for detailed information about the country's inspection practices and procedures to assist that country in organizing its materials. This information collection was approved under OMB number 0583-0094. The proposed rule contains no other paperwork requirements.

E-Government Act

FSIS and the U.S. Department of Agriculture (USDA) are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS

Committee) in Geneva, Switzerland, of this proposal and will announce it on-line through the FSIS Web page located at:
http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp.

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The Update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_&_Events/Email_Subscription/. Options range from recalls, export information, regulations, directives, and notices. Customers can add or delete

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List of Subjects in 9 CFR Part 381

Imported products.

For the reasons set out in the preamble, FSIS is proposing to amend 9 CFR part 381 as follows:

Part 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C 451-470; 7 CFR 2.7,
2.18, 2.53.

§ 381.196 [Amended]

2. Section 381.196 is amended in paragraph (b) by
adding "Republic of Korea" in alphabetical order to the list of
countries.

Done at Washington, DC, on: November 21, 2012

Alfred V. Almanza,
Administrator.

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